

**Amendment and Response**

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Serial No.: 10/019,643

Confirmation No.: 1109

Filed: December 28, 2001

For: METHOD AND COMPOSITION FOR AFFECTING REPRODUCTIVE SYSTEMS

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**Remarks**

The Office Action mailed May 5, 2004 has been received and reviewed. Claim 6 having been amended, the pending claims are claims 4, 6, 12-21, 23, and 27-29. Reconsideration and withdrawal of the rejections are respectfully requested.

**The 35 U.S.C. §112, First Paragraph, Rejection**

The Examiner rejected claims 4, 6, 12-21, 23 and 27-29 under 35 U.S.C. §112, first paragraph, because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Applicants respectfully traverse this rejection.

Specifically, the Examiner asserted that the specification, while being enabling for treating reproductive diseases that are related to egg laying or fertilization in birds, does not reasonably provide enablement for the treatment of neoplasia of the reproductive tract or cystic hyperplasia. The Examiner further asserted that the "specification provides no link between fertility and cancer, and it is has not been recognized by science that preventing fertility would treat cancers of the reproductive tract or cystic hyperplasia. In light of the lack of working examples or guidance as to how to practice the claimed invention to treat cancers by inhibiting fertilization, it would be unpredictable and require an undue amount of experimentation in light of the state of cancer to practice the full scope of the applicant's claimed invention" (page 2, Office Action mailed May 5, 2005).

Claim 6 has been amended to delete the recitation "neoplasia of the reproductive tract."

However, it is respectfully submitted that cystic hyperplasia is not a cancerous condition. Hyperplasia is an increase in cell number. Cystic hyperplasia, also known as simple or mild hyperplasia ("Robbins Pathologic Basis of Disease, Sixth Ed.," R.R. Cotran et al., Eds., "Cellular Adaptations of Growth and Differentiation, Endometrial Hyperplasia" at Chapter 24, page 1059,

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col. 2), is a benign condition that responds to regular growth control of cells. It is this response to normal regulatory control mechanisms that distinguishes hyperplasia from cancer (neoplasia) (Robbins Pathologic Basis of Disease, Sixth Ed., R.R. Cotran et al., Eds., "Cellular Adaptations of Growth and Differentiation, Pathologic Hyperplasia", *Cellular Pathology II*, 1999, Chapter 2, at p. 33, col. 2).

Hyperplasia of the reproductive organs is affected by fertility hormones and thus related to fertility. For example, endometrial hyperplasia is associated with an abnormally high, prolonged level of estrogenic stimulation and may be associated with anovulation (Robbins Pathologic Basis of Disease, Sixth Ed., R.R. Cotran et al., Eds., "Endometrial Hyperplasia" at page 1059, col. 1). In chickens, there is a very pronounced change in hyperplasia of the chicken oviduct during various stages of a reproductive cycle. Increases in cell numbers were observed in chicken magnum, isthmus, infundibulum, uterus and vagina during a reproductive cycle. (Yu et al., *Poultry Science* 53:1096-1105, (pp. 1096, col. 2, and 1104, col. 2).

It is therefore respectfully submitted that the conditions recited in claims 4, 6, 12-21, 23 and 27-29, as amended, are related to egg laying or fertilization, and that the claims are enabled by the specification. Reconsideration of the rejection of claims 4, 6, 12-21, 23 and 27-29 under 35 U.S.C. §112, first paragraph, is respectfully requested.

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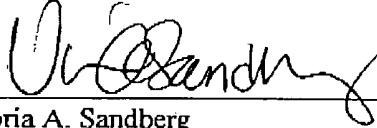
**Summary**

It is respectfully submitted that the pending claims 4, 6, 12-21, 23, and 27-29 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted for  
**FAYRER-HOSKEN et al.**


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**CERTIFICATE UNDER 37 CFR §1.8:**

The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 25 day of June, 2004, at 1:00 pm (Central Time).

By:   
Name: Sandy Truehart